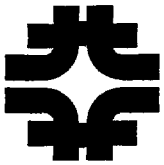

Fermi National Accelerator Laboratory

FERMILAB-TM-1953

Report on the Fermilab Pilot N&S Closure Process

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REPORT ON THE FERMILAB PILOT N&S CLOSURE PROCESS AUGUST 1, 1995

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REPORT ON THE FERMILAB PILOT N&S CLOSURE PROCESS AUGUST 1, 1995

INTRODUCTION

This report, prepared by Larry Coulson in behalf of the Convened Group, documents the Fermilab ES&H N&S pilot project conducted between February 27, 1995 and July 14, 1995. The pilot was charged with testing the validity and applicability of the Department of Energy Closure Process for Necessary and Sufficient Set of Standards, which we will call "the Process." (See Attachment 1.) Attachments to this report contain the key documentation and the results of the pilot. The most detailed source of documentation of the pilot is the *Documentation of Record* (DoR). The DoR comprises 10 appendices containing the detailed documentation, with an introduction, called the Process Documentation Guide, that describes the documentation in the appendices. The DoR Table of Contents and the Process Documentation Guide are Attachment 2 to this report. Another useful report is the *Fermilab Demonstration, Response to Criteria for Judging Success of Process Demonstration, July 25, 1995,* which contains the response to questions posed by the DOE Department Standards Committee to measure the success of the Fermilab pilot. The latter report, without attachments, is Attachment 3 to this report. Copies of the appendices and attachments to the above reports are available through the Director's Office at Fermilab (708-840-3211).

We intend this report for a broader audience than the other documents we reference above. We hope that this report will help guide others through the Process as currently written. We assume that the reader has an acquaintance with the Process and is using this report as a guide to its implementation. Without some prior acquaintance with the Process, we fear that many of the references will be meaningless.

The first of the eight parts of this report is this Introduction. The second part contains comments on the Process, including an explanation of the pilot organization. The third part, Implementation of the Process, describes what we did to address each section of the Process. This part should help the reader understand the interpretation chosen for each section of the Process. The fourth part contains a brief discussion of the contract modification made as a result of the pilot. The fifth part contains some general conclusions and lessons learned. The sixth part is a brief summary statement. The seventh section is a Glossary of Abbreviations, which the reader may find helpful in keeping track of the many abbreviations used in this report. Finally, there follows a series of 19 attachments, which contain the documentation to help the reader understand the details of the Fermilab pilot.

PROCESS COMMENTS AND ORGANIZATION

Comments

1. A critical element for the success of the pilot was the strong support from the entire line organization (ER, CH, BAO, and Fermilab), EH and the Department Standards Committee. Not only was there strong support and participation from all these organizations, but the working team relationship among the participants greatly facilitated the process.

2. From the beginning, the team decided to include all interested persons on the distribution list for documents as they were generated. Therefore, we sent electronic copies of meeting minutes, charters, etc. to everyone who had shown interest, including representatives of all the above-mentioned organizations. Ultimately over 40 people were on the distribution list.

3. Involvement of people and organizations outside the DOE family, peers from DOE sister labs, DOE personnel from the field office and area office, as well as Fermilab personnel, enhanced the credibility of the final product.

4. Agreement on the overall organization, responsibilities, authorities, etc. at the beginning of the Process kept the Process going smoothly. We agreed on the protocols for organization, approvals, responsibilities, and members of the Convened Group at the first and only meeting of the Extended Convened Group.

5. The Process works. We recognized that the Department Standards Committee had not specified the mechanics of the Process in great detail; but our experience showed that a strength of the Process comes precisely from the fact that the mechanics of the Process are *not* prescribed in great detail. Although this made starting the Process difficult, it allowed for enough flexibility for the responsible parties to implement the pilot in a way that reflected their collective judgment and experience. As a result, they felt comfortable in taking ownership of the Process and could feel confident of the results.

Organization

Attachment 4 shows the organization developed for the Fermilab pilot. The 3 boxes in the top row lists the **Agreement Parties**. The name within each box indicates the approval authority for that organization. Fred Bernthal is the President of Universities Research Association, Inc. (the organization that holds the contract with DOE to operate Fermilab);

John O'Fallon is the Director of the High Energy Physics Division in ER; and Andrew Mravca is the Manager of the Batavia Area Office, and the Contracting Officer.

Each of these organizations had one member on the **Convened Group** (the **Process Leader** is also from Fermilab but generally represented the Process and not an organization). Larry Coulson (Process Leader) is an Assistant Director at Fermilab; Ray Stefanski is the Associate Director for Operations Support at Fermilab; Andrew Mravca; and Dave Goodwin (ER-20) represented the Resource Authority.

The **Extended Convened Group** included the Convened Group members plus Cherri Langenfeld (Manager, Chicago Operations Office), Wilmot Hess (Director of High Energy and Nuclear Physics in ER), Ezra Heitowit (Vice President of URA), and Ken Stanfield (Deputy Director of Fermilab). This group met only once as a decision-making body. As described above, they created the overall plan for the Pilot.

A **Steering Committee** was created within Fermilab to advise the Process Leader on aspects of the Process that directly involved Fermilab. Members of the Steering Committee included Larry Coulson, Ray Stefanski, Bruce Chrisman (Associate Director for Administration), Don Cossairt (Head of the ES&H Section), Tim Miller (Deputy Head of the ES&H Section), Hans Jostlein (Standards Manager), and Kathy Williams (Manager of the QA Office).

The **Identification Team**, created by the Convened Group, consisted of 15 members including the Process Leader. One member each came from CEBAF, ANL, BNL, and BAO. Two members each came from SLAC and CH. The remaining members were Fermilab personnel. In general, senior personnel were chosen for their technical knowledge of accelerator activities, including ES&H aspects, and their ability to work in a team environment. The Identification Team broke into technical groups (by functional area), called **Focus Groups** ,to analyze issues and select standards. The Focus Groups had access to **Subject Matter Experts** as required.

The protocol for confirmation required presentation and defense of the draft set of standards to Fermilab first, and the Convened Group second. The Fermilab ES&H Policy Advisory Committee (**ESHPAC**), which advises the Director on ES&H Policy matters, primarily carried out the Fermilab review.

A **Confirmation Panel,** created to support the Convened Group in its challenge of the draft set, provided peer involvement at the confirmation stage. The Confirmation Panel included high-level operational and ES&H personnel selected from DOE and non-DOE laboratories with a history of accelerator based physics research.

IMPLEMENTATION OF THE PROCESS

This section follows the outline of the Process. Paragraph labels and headings are those used in the Process. We discuss the interpretation and implementation of each part of the Process, for the Fermilab pilot.

Definitions

We agreed on the following definitions at the Extended Convened Group meeting.

The **Customer Organization** is BAO.

The **Responsible Organization** is URA.

The **Agreement Parties** include URA, ER , BAO. This is in keeping with the suggestion to establish the approval authority as low in the organization as possible.

The **Resource Authority** is ER.

The Convened Group identified **Stakeholders** in a document called the Stakeholder Participation Plan. This plan defines stakeholders and indicates the level of involvement of each. (See Attachment 5).

Operational and Technical Experts were largely ES&H professionals, physicists, engineers and other line supervisors at Fermilab. We also tapped expertise at sister labs for participation on the Identification Team and the Confirmation Panel. Three local industrial companies participated by providing personnel to discuss their experiences with external regulation and regulatory bodies. In addition, the Safety Director of the Laboratory of Nuclear Studies at Cornell presented to the Identification Team his experience with safety issues and regulation by outside regulators.

1. INITIATING THE NECESSARY AND SUFFICIENT CLOSURE PROCESS

Initiation of the Fermilab pilot was somewhat different from that envisioned in the Process protocol document. Fermilab was selected by representatives of the Department Standards Committee and ER as a likely candidate to conduct the pilot for two important reasons: Fermilab is a single purpose laboratory and it is classified as a low hazard facility. It was anticipated that it would be easier to conduct the pilot at Fermilab than at a multipurpose or a higher risk lab. In a letter to Andrew Mravca, Wilmot Hess proposed that Fermilab conduct the pilot. Fermilab agreed, and sent a proposal to the Department Standards Committee. The Department Standards Committee accepted the proposal on 2/24/95. A kickoff meeting at Fermilab on 2/27/95 launched the pilot. Representatives of ER, EH, CH, BAO and Fermilab participated. The kickoff acquainted Fermilab managers and other Lab personnel with the Process and showed the support of the line organization and EH. We hoped that this would allay skepticism about the prospects for success of the pilot. As required by the Department Standards Committee's protocol for the pilots, the head of the ER program office, Martha Krebs, and the head of EH, Tara O'Toole, officially sanctioned the pilot. DoR Appendix A displays these letters.

The Responsible Organization, Fermilab, appointed Larry Coulson to be the Process Leader.

2. PRODUCING A NECESSARY AND SUFFICIENT SET OF STANDARDS

Process Element 1. Defining the Work and the Hazards

[1] Acquisition of relevant information on the work performed at Fermilab was obtained as follows:

A. Through the Convened Group meetings, the Process Leader solicited information on the initial conditions (A through F shown in paragraph [3]) from ER and BAO. The group agreed that the hazard (issue) identification survey to be conducted by Fermilab would supply the best "bottoms up" information. (See D.[3] below.)

B. Operational and technical experts provided much of the information collected by the survey conducted by Fermilab. Experts were also part of the Identification Team and the

Confirmation Panel as previously described. More than 30 Subject Matter Experts assisted the Identification Team.

C. The resource authority, ER, agreed that the pilot would be conducted within existing resource limits. The resources to conduct the pilot would come partially from delaying some reports to DOE. The resources for the Laboratory mission (HEP) were not an issue in this pilot. The group decided that, although resources would fluctuate, future resource availability would not play a role in this pilot.

D. The Convened Group defined Stakeholder involvement in the Stakeholder Participation Plan. The DoR, Appendix D, documents the involvement of stakeholders.

[2] The Process Leader organized all the collected information into a binder issued to each Identification Team member when the work of the Identification Team began.

[3] The primary source of information for the definition of work at Fermilab was a survey of management, supervisors, and ES&H professionals. The survey form includes questions A though F, some other questions, and a checklist of potential ES&H issues. Attachment 6 displays the survey forms. This information, collected from each of the 77 sub-organizational units at Fermilab, provided a characterization of all the work currently being done at the Lab. The DoR, Appendix C, contains the collected data. In addition to this survey, the Process Leader assembled other sources of information that were felt to be of importance in characterizing the work and hazards at the Lab—e.g. accident records, occurrence reports. Attachment 6 also documents the other sources of information.

The information from all these sources was formulated into 151 ES&H issues that were provided as a starting point to the Identification Team for analysis to produce the N&S set of standards. The DoR, Appendix E, displays this initial list of issues. Nearly everyone who reviewed this list agreed that, with only a few exceptions, the same list would characterize many light industrial companies. The obvious conclusion is that there are very few unique ES&H issues at Fermilab. Fermilab has mostly standard industrial hazards.

[4] Although the Process allows for re-evaluating the definition of the work if advised by the Identification Team, the team found no re-evaluation necessary.

Process Element 2. Creating the Team(s)

The Extended Convened Group named the members of the Convened Group as described above. The Extended Convened Group decided that it was appropriate for the Convened Group to consist of one representative of each of the agreement parties. We have earlier provided the membership of the Extended Convened Group and Convened Group, also included as Attachment 7.

The Convened Group followed the guidance in the Process as closely as possible. The Convened Group documented their decisions and the protocols for the pilot in the pilot Charter. (See Attachment 8.) The Convened Group carried out specific responsibilities as follows:

[1] The pilot Charter and the Identification Team Charter, Attachment 9, defined the criteria for selection of Identification Team members. The primary criterion for the Identification Team members was knowledge of the work activities at a research accelerator. Another criterion was work experience in an external regulatory organization such as OSHA or EPA. We agreed that a Fermilab person with technical expertise in the appropriate functional ES&H area should lead each of the Focus Groups of the Identification Team, so members from Fermilab were also selected on this basis.

[2] The Process Leader solicited biographies of candidates for the Identification Team from Fermilab, BAO, CH, and four sister labs (SLAC, ANL, CEBAF, and BNL). The Convened Group reviewed the biographies and selected the team members. Attachment 10 contains the names of the team members and a summary of their credentials.

The Convened Group approved a list of Confirmation Panel candidates from five sister labs and one non-DOE accelerator lab The Process Leader solicited the Confirmation Panel members from that list. The Confirmation Panel included the ES&H Managers from SLAC, LBNL, ANL, and the Deputy ES&H Manager from BNL. The Project Manager of CEBAF and the Safety Director of The Laboratory of Nuclear Studies, which operates the Cornell Electron Storage Ring accelerator at Cornell University, were also panel members. Attachment 10 contains the list of Confirmation Panel participants.

Process Element 3. Defining and Agreeing to Protocols and Documentation Requirements

[1] The Convened Group defined the protocols and documentation in the pilot Charter (Attachment 8). Of particular importance was the specification of the approval protocols, and resolution of differing opinions. The Extended Convened Group agreed that the approval would be by the Agreement Parties: President of URA, ER, and the Contracting officer, in that order. The process for resolving differing opinions followed the authority hierarchy—i.e. problems not resolved by the Identification Team would be referred to the Convened Group, problems not solved by the Convened Group would be referred to the Extended Convened Group. We defined no further appeal mechanism.

[2] The Convened Group left most decisions about the documentation of the Identification Team work to the Identification Team. The pilot Charter contains all decisions made by the Convened Group regarding documentation requirements.

The minutes of the meetings, contained in the DoR, Appendices E, F, and H, record Identification Team decisions about protocols and documentation.

Process Element 4. Identifying the Necessary and Sufficient Set of Standards

The Identification Team began its analysis on the 151 issues prepared as previously described. During their deliberations, some issues were deleted or combined with others and some issues were added, based on the Identification Team's professional judgment. Attachment 11 displays the final list of 172 issues. The Identification Team used the following process for the analysis of each issue:

1. The Identification Team determined if a standard is needed for each issue identified (either presented to them or identified by them).

2. If a standard is needed, a Fermilab Identification Team Document (FITD) was filled out. This form documented adherence to the requirements of the Process. In particular, it provides documentation of [2], [3], [6], and [7] in Process Element 4.

Attachment 12 shows a flow chart of the analysis process and an example of the FITD. More than 30 Subject Matter Experts, mostly drawn from Fermilab's pool of professional engineers, scientists, and ES&H personnel, assisted the Focus Groups in this analysis.

The expectations of BAO, ER, and URA for the pilot were primarily to use industrial solutions for industrial problems. In other words, if an identified issue is similar to that faced by industry and an industrial standard exists (e.g. OSHA, EPA, etc.) then that standard should be chosen. If no industrial solution exists or if it is inadequate, then another external standard is sought (e.g. consensus standard, DOE Order, etc.). Only if a satisfactory solution is not available from those choices should an internal (Fermilab) standard be chosen.

In order to help the team members better understand the consequence and experience of using industrial standards, the team asked several local industries and two university research facilities to participate. Three local industrial firms sent representatives to join in a panel discussion on industrial regulation and regulators. AMOCO Research Center, Amersham, and NALCO participated. The Safety Director of the particle accelerator at Cornell also visited the team and discussed his experience with ES&H at a high energy accelerator that is not subject to DOE regulations. The safety director for the accelerator facility at the University of Illinois (also not regulated by the DOE) sent a copy of the ES&H program developed for that facility for the Identification Team to review. The interactions with the representatives of facilities using outside regulation proved very insightful to the Team members.

Attachment 13 contains the final set of FITDs for all 172 issues, and Attachment 14 contains the final list of issues with corresponding standards citations. Some standards (e.g. OSHA 1910) had many sections referenced. In some of these cases the Identification Team decided to accept the entire standard for the sake of simplicity, even though some parts of it were not necessary for the set.

The Identification Team reached consensus on a set of standards. Attachment 15, the Team Report, contains these standards. The Identification team made no recommendations for redefinition of work or for developing new standards.

Process Element 5. Confirming the Necessary and Sufficient Set of Standards

The pilot Charter called for a two-step confirmation process. First, Fermilab was invited to review and comment on the draft set. The pilot Charter defines the protocols for this process, and DoR Appendix G contains the documentation of that review.

The Charter called for the final confirmation process to be a presentation and oral defense of the draft set by the Identification Team to the Convened Group. A peer group, the Confirmation Panel, assisted the Convened Group. The Convened Group also invited the Extended Convened Group to participate in the confirmation.

The Convened Group held the confirmation meeting on July 12, 1995. Attachment 16 shows the people participating. DoR Appendix I shows the minutes of the confirmation meeting, issues raised, and the resolution of those issues. During the meeting, three issues were raised that were significant enough to need resolution after the meeting. The Convened Group resolved all issues before approval of the N&S set of standards by the Agreement Parties.

Process Element 6. Approving the Necessary and Sufficient Set of Standards

Approval of the N&S set occurred on July 14, 1995. Attachment 17 contains the approval documents.

CONTRACT MODIFICATION

The DOE/URA contract was modified on July 14, 1995, as a result of the N&S Pilot (see Attachment 18). The contract modification replaced the existing list of applicable ES&H DOE Orders with a modified list of applicable orders and the "N&S" list of Standards.

The new contract no longer contains the orders for Quality Assurance, Conduct of Operations, Self-Assessment, and Maintenance Management. These management orders have historically been associated with the ES&H activities of laboratories. These orders are important because they affect the implementation of the N&S set.

The Convened Group asked the Identification Team to make recommendations about management systems to the Convened Group. However, the Identification Team could not reach consensus on the best management systems to use as "standards." Members of the team held views that reflected the management systems of their home institutions. Therefore, the Process Leader referred these issues to the Convened Group for resolution as per protocol in the Pilot Charter. The Convened Group discussed these issues with the Identification Team, the Confirmation Panel, and members of the Extended Convened Group present at the confirmation. It was noted that many of the selected standards explicitly addressed QA for ES&H—e.g. CFR 835.102, ASME Pressure Vessel Code, and the Handbook for Sampling & Sample Preservation of Water and Wastewater (EPA-600/4-82-029). The conclusion of the Convened Group was unanimous—the referenced orders do not add value and are not necessary; therefore the contract should not include them.

The following clause was inserted into the contract:

> 1,b,(3). (Fermilab will) Continue to maintain management systems that ensure that the agreed-upon standards are implemented.

This requires:

1. Fermilab to maintain adequate management systems, and
2. The Batavia Area Office to audit Fermilab's management systems.

Attachment 19 provides further details.

CONCLUSION AND LESSONS LEARNED

We conclude that the N&S Process works well as designed. We faithfully followed the sequence of steps for the N&S Closure Process, contained in the Charter for the pilot and in the Identification Team Charter. These documents provided an entirely satisfactory mechanism for getting the work done.

We also concluded that the role of the Process Leader is a critical and exacting one. The Process Leader's effective coordination of a complicated mix of working and advisory groups (the Convened Group, Extended Convened Group, Steering Committee, Identification Team, Focus Groups, and Focus Group Leaders) is vital to the successful implementation of the N&S Process.

We present below a collection of "lessons learned" from the implementation of the N&S Pilot Process at Fermilab; we hope that these remarks will help organizations that are planning their own N&S Process in the future:

- Time and Hard Work: A successful N&S Process requires a lot of hard work by highly qualified and highly motivated people. In particular, the Identification Team phase of the work required significantly more time and effort than the Process Leader had anticipated. If we count the time of all the persons (Fermilab, BAO, CH, ER, Department Standards Committee and outside persons) involved in meetings, preparation, follow-up, communication, travel, etc., we estimate that the pilot took about 90 person-months of effort. Fermilab effort was about 24 person-months. The direct cost to Fermilab (travel, facilitation, meeting rooms, materials, etc.) was about $50 K.

- Careful Organization: Careful organization of each step of the process, including faithful implementation of all of the prescribed formalities of the process, is very important. In the Fermilab Pilot Process, this organizational effort helped to prevent misunderstandings and contributed to assuring continued buy-in by all interested parties as work progressed. The efforts of the Process Leader to assure that all interested parties were kept informed throughout the process were most worthwhile.

- Facilitator: The participation of a management consulting firm in the Fermilab N&S Process was helpful, especially in its role as a process facilitator at the outset of the Identification Team's initial two week period of concentrated work in mid-May. The facilitator introduced several concepts (the use of flip charts, ground rules, specific goals, pre-determined breaks, role playing- devil's

advocate, a common understanding of the meaning of consensus, etc.) that proved very useful in keeping the Team and Focus Groups focused on the issues, the process, and the final objective.

- OSH Issues: The scope of the work of the Occupational Safety and Health (OSH) Focus Group was too broad. Over 100 of the ES&H hazard issues identified by the workers at Fermilab were in the OSH area. The assessment of these issues by at least two separate Focus Groups would probably have made a more effective arrangement.

- Boundary Conditions: Thoughtful consideration by the Process Leader, throughout the duration of the Identification Team work, of "boundary conditions" is important. It is not always clear what constitutes an ES&H issue, or if one should include a closely related topic associated with a particular ES&H issue. Examples of this are property loss prevention in the fire safety area, or safeguards and security considerations in the emergency response area.

- Involvement of Contract Lawyers: Although we solicited some comments from legal counsel early on, during the negotiations for the contract modification it became clear that more participation by the lawyers during the Identification Team process would have facilitated the final stages of the process.

SUMMARY

The Fermilab Pilot exercised the Process. The Pilot followed the Process scrupulously, and found it very useful for the intended purpose. A set of N&S standards was selected, approved and incorporated into the DOE/URA contract. We propose no changes to the Process. We recommend use of the Process by the other DOE laboratories. We feel that lack of resolve or vision of those involved would constitute the only barrier to success.

REPORT ON THE
FERMILAB PILOT N&S CLOSURE PROCESS

GLOSSARY OF ABBREVIATIONS

ANL	Argonne National Laboratory
BAO	Batavia Area Office (DOE) [Since renamed the Fermi Group]
BNL	Brookhaven National Laboratory
CEBAF	Continuous Electron Beam Accelerator Facility
CH	Chicago Operations Office (DOE)
DOE	Department of Energy
DoR	Documentation of Record
DSC	Department Standards Committee (DOE)
EH	Office of Environment Safety and Health (DOE)
EPA	Environmental Protection Agency
ER	Office of Energy Research (DOE)
ES&H	Environment Safety and Health
ESHPAC	ES&H Policy Advisory Committee (Fermilab)
FRMI	Fermi Group (DOE) [Formerly the Batavia Area Office]
FITD	Fermilab Identification Team Document
HEP	High Energy Physics
LBNL	Lawrence Berkeley National Laboratory
N&S	Necessary and Sufficient
OSH	Occupational Safety and Health
OSHA	Occupational Safety and Health Administration
QA	Quality Assurance
SLAC	Stanford Linear Accelerator Center
URA	Universities Research Association

THE DEPARTMENT OF ENERGY

CLOSURE PROCESS

FOR

NECESSARY AND SUFFICIENT

SETS OF STANDARDS

DRAFT 2D

3/16/95

FOR THE DEPARTMENT STANDARDS COMMITTEE

Closure Process for Necessary and Sufficient Sets of Standards

DRAFT

CLOSURE PROCESS FOR NECESSARY AND SUFFICIENT SETS OF STANDARDS

CONTENTS

Closure Process for Necessary and Sufficient Sets of Standards

DRAFT

OVERVIEW

The Department Standards Program promotes the use of standards that are supportive of work, rather than barriers or extra burdens. The "Criteria for the Department's Standards Program" establishes agreed upon, "necessary and sufficient" sets of standards for the performance of work as a keystone of the program. Criterion 6.3 states, "A Department-wide process establishes how Department line management and contractor management, at the organization level appropriate for effective management, approve and maintain a necessary and sufficient set of standards (including all requirements imposed by law) for Department operations." The Department Standards Committee has developed this draft "Closure Process for Necessary and Sufficient Sets of Standards," for use at any level, and by any organization within the Department complex, including the establishment of mutual contractual commitments between the Department and its contractors.

Standards are expressed expectations for the performance of work. Sources of standards include federal, state, and local laws and regulations; Department Orders; and other documents such as Department of Energy Technical Standards, nationally and internationally recognized consensus standards, and industry standards. **A necessary and sufficient set of standards** is one that (a) meets the performance expectations and goals for the work (including complying with laws and regulations and providing adequate protection to the environment, workers, and the public) and (b) contains only the standards which are necessary for the set to be sufficient.

The **closure process for necessary and sufficient sets of standards** described in this document is initiated when one or more of the criteria listed in Section 1 are met. The process begins with a definition of the work and the related hazards. Using this information and other Stakeholder input, an Identifying Team reviews existing standards and identifies which of them constitute a necessary and sufficient set. Additional standards are written if needed to achieve sufficiency. Closure of the process is achieved when the selected set of standards is confirmed and approved.

The Fermilab Necessary and Sufficient ES&H Pilot utilized Draft 2, 2/24/95 of the Closure process document. There are no substantive differences between the 2/24/95 draft and this draft.

Closure Process for Necessary and Sufficient Sets of Standards

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DEFINITIONS

The **Customer Organization** is the organization that has direct responsibility, accountability, and authority for having the work performed subject to the agreed-upon set of standards.

The **Responsible Organization** is the organization that has direct responsibility, accountability, and authority for performing the work subject to the agreed-upon set of standards.

An **Agreement Party** is any party, including, at a minimum, the Responsible Organization and the Customer Organization, who must agree to the necessary and sufficient set of standards for the work (for example, parties to a contract, as in the case of DOE and a M&O contractor, or management organizations within an agency or company that agree on standards for performance of work.)

A **Stakeholder** is any party other than the Resource Authorities or the Agreement Parties that will be materially affected by, or can materially affect, the outcome of the work, either favorably or unfavorably (for example, representatives of state, local, and federal governments; labor unions; and citizens' groups.)

Operational Experts are individuals with knowledge and expertise relevant to the work, and the site, facility, and activities addressed by the necessary and sufficient set of standards.

Technical Experts are individuals with knowledge and expertise relevant to a particular environment, safety and health discipline, for example, industrial hygiene, criticality control, or industrial safety.

Resource Authorities are organizations or individuals who have control over the equipment, facilities, personnel, and budget necessary to accomplish the work. Line managers are typical resource authorities in classical organizations. Program and project managers are typical resource authorities in matrix organizations. Some organizations may have resource managers who are independent of programs and projects.

Closure Process for Necessary and Sufficient Sets of Standards

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1. INITIATING THE NECESSARY AND SUFFICIENT CLOSURE PROCESS

Objective: to determine whether the criteria exist for initiating the necessary and sufficient closure process and to assign responsibility for conducting the process.

The criteria for initiating the necessary and sufficient closure process are as follows:

A. A set of standards does not exist, as in the case of a new activity;

B. An existing set of standards (for example, the current set of all applicable Department directives) is no longer appropriate due to changes in mission, regulatory environment, degree of hazard, performance expectations, or knowledge;

C. The applicable contract requires that the process be used;

D. A Stakeholder demonstrates that the existing set of standards is NOT necessary and sufficient. A Stakeholder must demonstrate to the satisfaction of the agreement parties that the set of standards being used is not sufficient to provide adequate protection. Demonstration is to be made through evidence that shows the set of standards, not a lack of effective implementation of the standards, is the reason for not providing adequate protection.

The **Agreement Parties** are responsible for determining if any criteria for initiating the necessary and sufficient closure process is satisfied.

If an Agreement Party determines that at least one of the criteria is satisfied, the **Responsible Organization** assigns responsibility for conducting the process to a Process Leader.

NOTE: Criterion 6 states that identification, approval and maintenance of necessary and sufficient sets of standards will be at the organizational level appropriate for effective management. With regard to the conduct of the closure process, this will be at the lowest level of management that has responsibility for managing the work affected by the necessary and sufficient set of standards. This closure process is intended to be general enough to be applied at any management level within the Department and its contractor complex. It can be applied to establish contractual standards, or to the development of standards within a contractor organization, e.g., work standards for a specific work task.

Closure Process for Necessary and Sufficient Sets of Standards

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2. PRODUCING A NECESSARY AND SUFFICIENT SET OF STANDARDS

Objective: to produce and reach closure on the necessary and sufficient set of standards to meet performance expectations and objectives for providing adequate protection to workers, the public, and the environment. This phase consists of the following five major process elements:

1. Defining the work and the hazards

2. Creating the team(s)

3. Defining and agreeing to protocols and documentation requirements for the teams

4. Identifying the necessary and sufficient set of standards

5. Approving the necessary and sufficient set of standards.

These process elements do not need to be performed sequentially. Any one or more of them can be accomplished concurrently. Also, as the process evolves, it may be necessary to iterate among the various elements to allow for any changes to the scope, expectations, teams, set of standards, or other efforts being conducted within the process elements.

Process Element 1. Defining the Work and the Hazards

Objective: to define the work to which the standards apply.

This process element is critical to the successful identification of a necessary and sufficient set of standards. Without a clear definition of the work and its associated hazards and uncertainties a set of standards may be insufficient to provide the desired level of protection or may contain more standards than needed and be inefficient and wasteful of resources.

Closure Process for Necessary and Sufficient Sets of Standards

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In this process element, the **Process Leader** has the four following responsibilities:

[1] Acquire relevant information on the work to be performed from the following involved parties:

A. Agreement Parties. Individuals representing the Agreement Parties will provide information on initial conditions [3]A through [3]F.

B. Operational and Technical Experts will assist the Agreement Parties in providing information on initial conditions [3]A through [3]F.

C. Resource Authorities will provide information on initial condition [3]G.

D. Stakeholders who can and want to contribute to the work of this Process Element. These Stakeholders may include officials of the state or city and county governments located adjacent to a Department site or facility; unions representing labor at the site or facility; local citizens' groups, and independent oversight organizations within the Department and the contractor organization. They will provide information on initial conditions [3]H and [3]I.

[2] Organize the information received from the above parties as an initial basis for identifying the necessary and sufficient set of standards.

[3] Define the work in terms of these initial conditions:

A. Performance expectations and objectives (for example, goals for safety, quality, and operations).

B. What actions will be performed.

C. Physical conditions within which the work will be performed.

D. Materials and conditions that could cause adverse consequences (for example, hazards, carcinogens, and radiation).

E. Uncertainties about the work.

F. Organization and management.

G. Resource availability and constraints.

H. Stakeholder concerns.

Closure Process for Necessary and Sufficient Sets of Standards

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I. Stakeholders' channels of communication.

[4] If necessary, re-evaluate the work definition on the basis of feedback from the team(s).

Process Element 2. Creating the Team(s)

Objective: to create one or more teams that will develop a necessary and sufficient set of standards and confirm that the set is adequate and feasible.

The establishment of a set of standards relies on the collective judgment of a team of knowledgeable people in reaching a decision on what constitutes a necessary and sufficient set of standards for a defined scope of work. The nature of the work, its complexity, hazards, and uncertainties will determine the breadth of knowledge needed within the team. To ensure that a) the criteria for the team(s) members reflect the full breadth of issues to be addressed, and b) that resources for establishing the teams are provided, a group of interested parties will be used to establish the criteria for team members, and to arrange for individuals to be assigned to the team.

The use of a team for confirmation of the necessary and sufficient set of standards is intended to provide an adequate basis for approval of the set. The criteria for the team members, and the degree of individual and team independence needed for this purpose will have to be determined by the convened group in each case. For simple cases, the identification process itself may provide sufficient evidence of the adequacy and feasibility of the set. For more complex or controversial cases, it will be necessary to use more rigorous and independent methods for confirmation, for example, a formal, independent peer review. When formal, independent peer review is deemed desirable, NUREG-1297, "Peer Review for High Level Waste Depositories," may be useful.

The **Process Leader** will convene a group with representatives of

A. The Agreement Parties

B. The Resource Authorities

C. Stakeholders who have indicated that they want to participate and can be expected to contribute to the development of a necessary and sufficient set of standards. In most cases these Stakeholders include officials of the state or city and county governments located adjacent to a Department site or facility.

Closure Process for Necessary and Sufficient Sets of Standards

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The **Convened Group** will have the following responsibilities:

[1] Define the criteria for the team(s) that will be formed.

A. Establish the functions, relationships, and composition of the team(s) based on (1) the complexity of the work or the existing set of standards to be reviewed; (2) the number of disciplines (technical and otherwise) involved; and (3) the extent to which the relevant technical, scientific, programmatic, and Stakeholder communities are known to hold differing opinions on the issues under review.

B. Establish membership criteria pertaining to

Qualifications for Technical Experts (Subject Matter Experts) and Operational Experts, who have experience doing the work.

Those groups/interests that will be represented, including Resource Authorities and Stakeholders as appropriate (for example, representatives of state, local, and federal governments; labor unions; and citizens' groups.)

[2] Arrange for individuals to be assigned to the team(s), consistent with the membership criteria. (Assignment of people to the team means that members will fully participate in all team meetings and team decision making.)

Process Element 3. Defining and Agreeing to Protocols and Documentation Requirements

Objective: to establish protocols, agreements, and documentation requirements for a credible and efficient process.

NOTE: The degree of formality and the extent of documentation required may vary, depending on the work and the following considerations: (A) The potential impact of the identified hazards and associated uncertainties of the work; (B) The degree of Stakeholder involvement; (C) The complexity of the work; and (D) The quality and rigor required to provide confidence that the standards selected meet the performance expectations and objectives of the work.

Closure Process for Necessary and Sufficient Sets of Standards

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In this process element, the **Convened Group** will have the following responsibilities:

[1] Establish the following protocols and agreements, as necessary

A. Who will approve the final set of standards.

B. Schedules, time limitations, and approval defaults. (Approval defaults are automatic approvals of the set when the approval authorities do not take timely action in accordance with the time duration established for their review and approval.)

C. Resolution of differing opinions.

D. Interactions between this group and the teams.

[2] Establish the following documentation requirements, as necessary, for

A. The format and content for plans and procedures. (Typical plans and procedures may include: a plan for carrying out the closure process including a schedule for completion of the process activities, a plan for performing a formal peer review, a procedure for how comments and differing opinions are to be resolved, and a procedure for how team member qualifications are to be documented.)

B. The responsibilities and qualifications of team members.

C. Team consensus and differing opinions.

D. Decisions relating to the following:

Initiating the necessary and sufficient process.

Defining the work.

Selecting the team.

Selecting and confirming the standards.

Approving the necessary and sufficient set of standards.

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E. The basis for what constitutes a necessary and sufficient set of standards, including, at a minimum:

Definition of the work and hazards.

Compilation of the necessary and sufficient set of standards.

Justification for the set's adequacy.

Implementation assumptions necessary for reaching closure on the set, which will be used in interpreting and applying the set (e.g., any unique additional resource requirements, or any time constraints for the use of certain selected standards).

The **Process Leader**, with the participation of team members, will have the following responsibilities to carry out the duties assigned by the Convened Group:

NOTE: It is intended that the team perform its activities face-to-face as a group in determining what is judged to be the necessary and sufficient set of standards. All members of the team are expected to be present for team meetings and participate in team decision making.

[1] Establish the following team protocols, as necessary for

A. Establishing team members' roles and responsibilities.

B. Orienting team members on the necessary and sufficient process.

C. Developing plans and procedures, including schedules and cost estimates.

D. Resolving comments and differing opinions. In those cases where differences in opinion cannot be resolved within the team, dissenting opinions will be documented for consideration by the confirmation team (if any) and the approval authority.

E. Interacting with Stakeholders when it is necessary to obtain clarification of Stakeholder concerns included in the definition of work and hazards.

[2] Establish any additional team documentation requirements, as necessary.

Team Members must conduct the process in accordance with the protocols and documentation requirements.

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Process Element 4. Identifying the Necessary and Sufficient Set of Standards

Objective: to identify and reach team consensus on the necessary and sufficient set of standards.

The team assigned to identify the necessary and sufficient set of standards draws upon its collective experience to achieve the objective.

The **Identification Team** has the following eight key responsibilities:

[1] Identify any additional information needed to define the work.

[2] Evaluate relevant sources of existing international, national, state, local, and work-specific standards including laws, regulations, rules, orders and procedures.

[3] Identify which of the existing standards constitute a necessary and sufficient set, or write additional standards as needed to achieve sufficiency, with the requirement that only those standards necessary to provide adequate protection of workers, the public and the environment are included in the necessary and sufficient set.

[4] Request additional resources, if needed, such as other subject matter experts or resource authorities.

[5] Reach consensus on the necessary and sufficient set of standards.

[6] Identify (A) any assumptions used by the team regarding implementation of the necessary and sufficient set to achieve consensus (for example, use of a procedure where there is no established standard for a certain type of operation); and (B) the team's views on any unique resources required to implement the set of standards.

[7] Identify those applicable federal, state, and local laws, regulations, and rules that are required to be included in the necessary and sufficient set of standards, but are judged not to add any value to the achievement of adequate protection. This identification will serve as the basis for pursuing exemption from these standards.

NOTE: No justification or documentation is required for applicable non-regulatory standards that are NOT selected (for example, DOE Orders, manuals, and technical standards, and industry consensus standards.)

Closure Process for Necessary and Sufficient Sets of Standards

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[8] If it is not possible to identify a necessary and sufficient set to meet the current performance expectations and objectives, an outcome of the process may be to recommend that the work definition be revised, or that new standards be developed, or both.

If it was determined in Process Element 2, "Creating the Team(s)," that a separate confirmation team will be needed to provide an adequate basis for approval, the confirmation team will proceed as follows:

[1] Review the information available to and used by the Identification Team.

[2] Confirm that the set of standards is necessary and sufficient to satisfy the performance expectations and objectives of the work.

[3] Confirm that implementation of the set of standards will be feasible.

NOTE: Although it is always necessary to provide confirmation, it may not be necessary to have an independent confirmation team.

If the actions performed in this process element meet their objective and conform to the applicable protocols and documentation requirements, then the **Process Leader** initiates Process Element 5.

Process Element 5. Approving the Necessary and Sufficient Set of Standards

Objectives:

A. To accept the level of protection provided by the necessary and sufficient set of standards.

B. To accept and authorize the use of the necessary and sufficient set of standards, including any implementation assumptions.

NOTE: This approval does not constitute approval of exemptions to applicable laws and regulations. Process Element 4 provides that those standards, in laws and regulations, that do not provide any value to protection of workers, the public and the environment will be identified as a basis for seeking exemption through the prescribed processes.

Closure Process for Necessary and Sufficient Sets of Standards

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The **approval authority** will

[1] Judge whether the necessary and sufficient process has been correctly implemented.

[2] Determine whether the confirmation provided by Process Element 4 is adequate to support approval. If this confirmation is not adequate to support approval, the approval authority may request that the deficiencies be corrected, or to initiate its own confirmation action.

[3] Approve or disapprove the set of standards in accordance with the established time limitations or approval defaults.

NOTE (1) *This approval constitutes a commitment to provide the necessary resources through the normal budget process.*

NOTE (2) *Criterion 6 states that identification, approval and maintenance of necessary and sufficient sets of standards will be at the organizational level appropriate for effective management. With regard to the approval of necessary and sufficient sets of standards, this will usually be at the lowest level of management that has responsibility for managing the work affected by the necessary and sufficient set of standards and for managing the resources needed to perform the work.*

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NOTE: WHILE ESSENTIAL, THE ACTIVITIES DESCRIBED IN THE FOLLOWING TWO SECTIONS ARE NOT CENTRAL TO THE NECESSARY AND SUFFICIENT CLOSURE PROCESS AND THEREFORE ARE NOT DESCRIBED IN DETAIL.

3. INCORPORATING THE NECESSARY AND SUFFICIENT SET OF STANDARDS IN WORK PLANNING AND ACCOMPLISHMENT

To ensure that the expectations and agreements established between the Responsible Organization and the Customer Organization are successfully implemented, the **Responsible Organization**:

A. Ensures that the necessary and sufficient set of standards and associated implementation assumptions become the operating basis for all activities covered by the set.

B. Performs any agreed-upon actions which were approved with the set.

Methodologies for achieving these objectives are defined in existing business practices. Further definition is not central to the standards identification and closure process and therefore is not provided in this document.

Closure Process for Necessary and Sufficient Sets of Standards

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4. EVALUATING WORK PERFORMANCE AGAINST THE NECESSARY AND SUFFICIENT SET OF STANDARDS

In order to create confidence in the agreed-upon necessary and sufficient set of standards and the process used to reach closure on the set, continuous assessment and feedback will be provided by the approval parties on the following:

A. Whether performance expectations and objectives established during the necessary and sufficient closure process as measured by the approval parties are being met.

B. Actual work performance as measured by the approval parties.

C. The adequacy and feasibility of the necessary and sufficient set of standards as determined by the approval parties.

D. The adequacy and effectiveness of various process elements within the necessary and sufficient closure and implementation processes.

These objectives are expected to be accomplished through existing practices. Further definition of these practices is not central to the standards identification and closure process and therefore is not provided in this document.

Fermilab Necessary and Sufficient ES&H Standards

Documentation of Record

July 14, 1995

Larry Coulson, Process Leader

Fermi National Accelerator Laboratory

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U.S. Department of Energy

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PROCESS DOCUMENTATION GUIDE

Initiating the Process

The implementation of the N&S pilot process at Fermilab was initiated by a February 23, 1995 memorandum from Wilmot Hess (ER-20) to Andrew Mravca (Manager, BAO). This activity was subsequently authorized by Martha Krebs (ER-1) and Tara O'Toole (EH-1). See Appendix A.

On 2/24/95 application for initiating the Pilot was submitted to and approved by the Department Standards Committee. On 2/27/95 a kickoff meeting was held at Fermilab to explain the process to Lab representatives and begin organizing the pilot. At that meeting the Responsible Organization named Larry Coulson the Process Leader.

Organization

The Chicago Operations Manger, Cherri Langenfeld, The Contracting Officer, Andrew Mravca, Director of HENP, Bill Hess, and the Deputy Director of Fermilab, Ken Stanfield, (later this group and some of their staff was named the Extended Convened Group) met and chose the members of the Convened Group. See Appendix B.

The Convened Group for the Fermilab Pilot N&S Process met several times to establish the protocols for the Pilot and create the Identification Team, and fulfill all the other requirements for the Convened Group as defined in Process Elements 1, 2, and 3. The minutes of the CG meetings and the other documents generated to document the process are displayed in Appendix B. The CG created and charted the IT as required in Process Element 2. The charter and list of IT members is displayed in Appendix B.

Hazard Identification

The Process Leader solicited information necessary to define the work to which the standards will apply. A bottoms-up, worker safety oriented "Hazard Identification Process" was employed by Fermilab to develop an initial list of hazard issues at the Laboratory. This list of hazard issues was the starting point for determining the set of N&S ES&H Standards for Fermilab. See Appendix C. Additional sources of

information used in developing and verifying the hazards issues list is also included in Appendix C. The list of issues given to the Identification Team is in Appendix E.

Stakeholders

Stakeholders were identified early and a document prepared to define the involvement of the stakeholders in the process. The Stakeholder Communication Plan and copies of all stakeholder input received is displayed in Appendix D.

Identification Team Meetings and Fermilab Review

The Identification Team met on three occasions. At its first and longest meeting, from May 8 to May 19, the Team reviewed all of the hazard issues which had been compiled by the Laboratory, and developed a draft set of ES&H standards for each of these issues. Each hazard issue was reviewed by one or more Identification Team "Focus Groups" (six sub-groups of the Identification Team, which were charged with identification of ES&H standards in six topic areas -- fire protection, radiation protection, environmental protection, occupational safety & health, emergency response, and management & oversight issues). The Focus Groups were assisted in their work by a number of specialized "Subject Matter Experts" (SMEs). The work of the Focus Groups was accomplished through a deliberative process represented by the fourteen parts of the "Fermilab Identification Team Documentation" (FITD) analysis report forms on which the results of the hazard issue analyses and ES&H standards identification processes were documented. Appendix E contains minutes of some of the meeting, a list of subject matter experts, the draft set, the Final FITD Forms, and Final Simi-Rolled-Up List of standards.

At its second meeting, on June 13 and 14, the Identification Team reviewed the consolidation and completion of the FITD forms and the development of a draft Set of N&S Standards which had been carried out by the Focus Group Leaders in the interim period; the Team also reviewed a first rough draft of a Team report. The Team reached consensus, as follows, on June 14: "The FITD Forms and the draft set of standards resulting from the FITD Forms are sufficiently close to final form that, with suggested changes, they may be sent for the next level of review, i.e. review by Fermilab, and the development of the (Team's) report will continue taking into account the guidance

received from the Team members." Appendix F has documentation of the second Identification Team meeting.

During the week of June 26, the draft Set of N&S Standards was presented to Fermilab for review in a series of meetings. The documentation of the meetings, issues raised and issue resolution is in Appendix G.

At its third meeting, on July 11, the IT reviewed the resolution of comments received since it last met and approved the Final Team Report which was presented at the Confirmation Meeting. Documentation of the third IT meeting and the Final Issue List is in Appendix H.

Confirmation and Approval

On July 12, the report and draft Set were presented to the Convened Group for confirmation. Documentation of the Confirmation Meeting, issues raised, and issue resolution is in Appendix I.

On July 14, the Agreement Parties approved the set of N&S Standards. At the same meeting the DOE-URA Contract was modified to incorporate the N&S Standards. Documentation of approval and the contract modification are in Appendix J.

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Director's Office

July 25, 1995

Ms. Margaret H. Sturdivant
U.S. Department of Energy
EH-31, 329/CXXI
19901 Germantown Road
Germantown, MD 20585

Dear Ms. Sturdivant:

I wish to express my gratitude for all the help, encouragement, and advice that you, David, Dennie and others on your staff gave us during the Fermilab Pilot. Without that support we could not have succeeded.

I know that the DSC is searching for ways to assure themselves that the Pilots are a success when they finish. I have enclosed a report, (Fermilab Demonstration, Response to Criteria for Judging Success of Process Demonstration, July 25, 1995) which provides responses to questions developed by the SPAT 3/4. This report and the attachments should help provide a picture of the process used for implementation of the N&S process at Fermilab.

Please feel free to share the enclosure as appropriate.

Thanks again for your help.

Yours truly,

Larry, Coulson, Process Leader

LC:sa

Enclosure: As stated.

cc: R. Stefanski, w encl.
R. McCullum, w encl.
D. Goodwin, w encl.
A. Mravca, w encl.
E. Heitowit, w encl.

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Fermilab Demonstration
Response To Criteria
for
Judging Success of Process Demonstration
July 25, 1995

This document provides responses to questions prepared by the SPAT 3/4 of the DOE Department Standards Committee to gain a measure of the success of the Fermilab Demonstration of The Department of Energy Closure Process for Necessary and Sufficient Sets of Standards. The Fermilab Pilot was begun on February 27, 1995 and concluded with approval of a set on July 14, 1995. In addition to answering the questions, many documents are attached to provide a clear picture of the process as executed at Fermilab. Additional, more detailed, documentation is available in the Documentation of Record. The table of contents of the Documentation of Record is Attachment A to this document. Documents in the Documentation of Record are available from Fermilab. Currently these can be obtained by contacting Larry Coulson at 708-840-5242 (FAX: 708-840-2939; E-Mail: COULSON@FNAL.GOV).

Process Element 1 - Defining the Work and Hazards

- **Was the objective of the demonstration clearly defined?**

  Yes, the objective was defined in the demonstration's Charter as follows:

  > "The result of this pilot will be a set of standards which will serve as the agreed upon basis for providing FNAL with adequate Environment, Safety and Health Protection at the lowest possible cost. This pilot will seek out and emulate compatible industry practices which have been proven successful both in terms of safety performance and cost-effectiveness."

- **Was the work scope adequately defined?**

  Yes, the work scope was defined as all work done at Fermilab.

- **Were the various work hazards identified?**

  Yes, an extensive hazards identification process was employed. All work units at the lab were surveyed and asked to identify the hazards associated with their jobs. About 150 hazards and other ES&H issues (issues) were so identified. The results of this effort were combined with the results of other analysis efforts and evaluated by the Identification Team based on their knowledge of Fermilab's work to arrive at the final list of 172 hazards. Attachment B contains the issues list in its final form as it was at the end of the demonstration.

- **Were safety, environment, quality and operational goals identified?**

  Yes, Fermilab expects to be in the upper quartile of accident/incident and environmental protection experience for comparable industrial situations. The accident/injury record indicates this performance goal is already met.

- **Were resource availabilities and constraints identified and incorporated into the process and goals?**

  It was understood that the process itself would be conducted within existing resources. The customer and resource organizations adjusted their expectations for other things which could have been done with the same resources accordingly. It was also understood that any process result which would cause the laboratory to be more expensive to operate was not a desired result.

Process Element 2 - Creating the Teams

- **Were organization and management relationships identified and considered?**

  Yes, this was the purpose of the "Expanded Convened Group". This group consisted of senior DOE and URA officials from all relevant organizational

and management entities. It was through the agreement of this group, based on their consideration of such relationships, that the approval authority was established and empowered to conduct the process. These relationships are reflected in the way the demonstration itself was organized. Attachment C is a copy of the organization developed for the demonstration.

- **Were requirements for team functions, relationships and composition established and implemented?**

  Yes, these were established in the demonstration's charter (Attachment D) and the Identification Team Charter (Attachment E). The minutes of the Convened Group and Identification Team and the Team's Final Report show that these requirements were followed.

- **Were team members selected on basis of technical credentials and/or work experience?**

  Yes, both. Resumes were solicited for Identification Team membership by the Convened Group. The Convened Group reviewed these resumes to determine adequacy of technical credentials and assure that the team would have work experience in every one of the functional areas which would need to be covered. The Team Charter documents the requirements.

- **Were outside technical experts added to the team when internal expertise was not available?**

  Yes, a special effort was made to involve persons outside the organizations of the Agreement Parties. The Identification Team included members from 4 other DOE peer laboratories. The Confirmation Panel consisted of representatives of 5 DOE peer laboratories. The Identification Team utilized 31 subject matter experts from Fermilab. Representatives from 2 universities were involved--one participated in both the Team work and confirmation and the other sent ES&H material. Representatives of 3 nearby, private sector companies conducting work similar to that done at Fermilab participated in a panel discussion to educate the Identification Team on how their companies

deal with ES&H issues, management of ES&H, and interactions with external regulatory agencies.

- **Were outside technical experts added to the team for confirmation?**

  Yes, the confirmation was a two step process. Fermilab was given a chance to review and comment of the draft set. This involved many of the Fermilab experts and the top management through the ES&H Policy Advisory Committee.

  A confirmation panel consisting of experts from 5 DOE laboratories and 1 non-DOE laboratory along with the "Convened Group" and "Extended Convened Group" was assembled to review the set and participate in the confirmation meeting where the panel's instructions were to "challenge" the set. This oral challenge of the set was a structured question and answer session analogous to a thesis defense. Each member of the panel was given opportunity to raise issues concerning the set, all issues raised were resolved prior to approval.

Process Element 3 - Defining & Agreeing to Protocols & Documentation

- **Did the process leader carry out the actions in the process description?**

  Yes, the process leader comprehensively implemented all elements of the process and rigorously documented that this was done. All of this documentation is contained in the Documentation of Record.

- **Were all relevant parties identified and provided opportunity to participate?**

  Yes, the "convened group" consisted of representatives of each of the 3 agreement parties (responsible organization, customer organization and resource authority) and the process leader. Consideration to all other relevant

parties was provided for though the much broader "extended convened group". Relevant parties also participated on the Identification Team and played a part in the confirmation process. Attachment F is the membership lists of the Identification Team and the Confirmation Team.

- **Did the Agreement Parties identify relevant work planning participants (stakeholders)?**

  Yes, a participation plan was developed by the Convened Group to address all stakeholder relationships. The plan and a report on the participation of each group is in Attachment G.

- **Were protocols established for conducting the process?**

  Yes, a Process Charter (Attachment D) was developed and agreed to by the Convened Group containing all relevant protocols.

- **Were protocols established for resolving differing opinions?**

  Yes, this was specifically addressed in the Process Charter and built into the pilot's organizational structure.

- **Were documentation requirements established?**

  Yes, this was specifically addressed in the Process Charter.

- **Was information recorded in conformance with documentation requirements?**

  Yes, this is documented in the Documentation of Record.

Process Element 4 - Identifying the Necessary and Sufficient Set

- **Was the work scope (if adjusted) clearly defined and were hazards clearly identified?**

  The Fermilab work scope did not need to be adjusted to identify a necessary and sufficient set of standards.

- **Was the Necessary and Sufficient Set compiled in an understandable format?**

  The set was compiled in a format that was convenient for participants and for the contract modification. However, others found it somewhat difficult to use. Improvements can be made based on the comments of others. The set is contained in Attachment H.

- **Did the team provide justification for the adequacy of the Necessary and Sufficient Set?**

  Yes, it was shown that each identified issue at Fermilab was adequately covered by a standard or standards included in the set. This was documented on a Fermilab Identification Team Document (FITD) for each hazard. The full final set of FITDs are in the Documentation of Record. Attachment I is an example of a completed form. Also the final Team Report, Attachment J, addresses this issue.

- **Were implementing assumptions needed to reach agreement on the set?**

  Only one, which concerned management systems and was addressed by including language in the contract modification associated with the set. Nearly all of the standards in the set are already part of the Fermilab ES&H program and thus represent very little new to implement.

- **Was a unanimous agreement reached on the set or were there dissenting opinions?**

  The agreement was unanimous. This is attested to by the fact that all members of the identification team signed the set (see Attachment J), with no added comments, and were present at the confirmation meeting to defend it.

- **Were applicable laws and regulations judged not to add value identified?**

  Yes, evaluations of the value added by specific standards were made on every one of the FITD forms. Examples where non-value added laws and regulations were identified are in Attachment K.

Process Element 5 - Approving the Necessary and Sufficient Set

- **Did the Approval Authorities document that the principles of the Process had been followed?**

  Yes, the demonstration's adherence to the process is described in the approval documentation which was signed by these authorities in approving the standards set. (See Attachment L.)

- **If there were implementing assumptions, were they reasonable?**

  Yes, the only implementing assumption was the contractual expectation that Fermilab have in place appropriate management systems so that the set could be implemented. Considering the good track record of this laboratory's management, this seems reasonable. As mentioned earlier, implementation will not be difficult as most all standards are already part of the ES&H program.

- **Was there a dissenting opinion at the time of approval?**

  No

- **Did the Approval Authority affirm that confirmation of the set is adequate to support approval?**

  Yes, each of the approval authorities was either present or represented at the confirmation meeting. At the conclusion of the confirmation meeting all attendees agreed that, pending resolution of 3 open issues, they considered the set adequately confirmed. Each of these issues was resolved to the satisfaction of those raising the issues prior to approval of the set.

- **Was the Necessary and Sufficient Set approved?**

  Yes, by signature of all approval authorities. (See Attachment L.)

Fermilab N&S Pilot Organizational Structure